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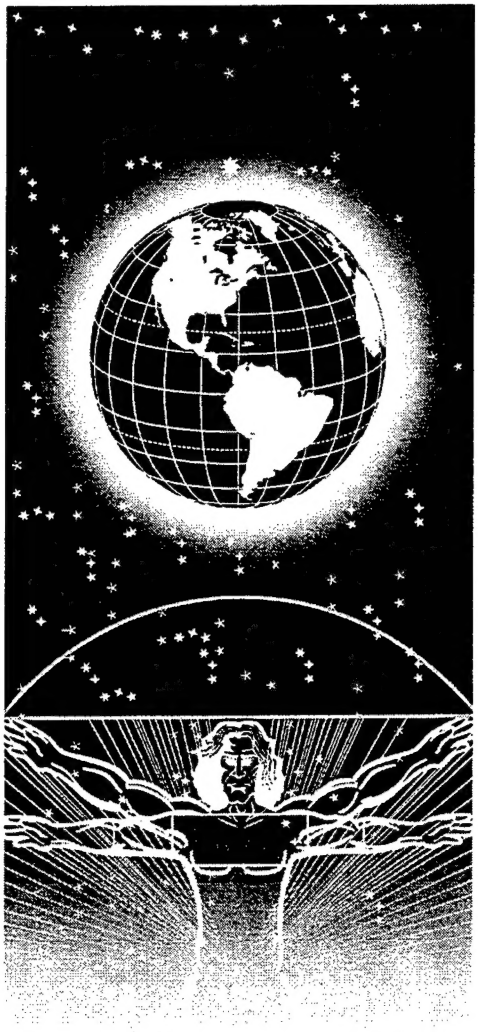

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE IVAC MEDSYSTEM III MULTI-CHANNEL INFUSION PUMP AND IVAC AC POWER ADAPTER, MODEL 1555

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June 1998

NOTICES

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The MedSystem III is a multichannel infusion pump which has three independent fluid delivery systems in the space of one. The MedSystem III provides an accurate delivery of a variety of fluids, and uses administration sets that provide free flow protection. The MedSystem III displays infusion status for rate, volume remaining and volume infused. The rate range is from 0.1 - 999 milliliter per hour on each channel. Infusions can be programmed to deliver at a specified rate or over a specified period of time. Secondary mode allows fluids and medication to be delivered sequentially at two different rates. Configuration parameters allow the user to essentially have six available device types to achieve specific clinical applications: General Purpose, Neonatal, Controller Pressure, Operating Room, General Purpose II, Operating Room II. The different parameters include minimum rates, baseline and minimum volumes, baseline and maximum pressures, and air-in-line thresholds. The MedSystem III operates on 115 VAC/60 Hz, and an internal rechargeable battery pack. The MedSystem III weighs approximately 5.1 lbs (2.32 kgs), and is 6 in. W. X 7.875 in. H. X 2.10 in. D. The MedSystem III has an integral pole clamp that may secured to a NATO litter handle (pole) or a C-9 litter stanchion. The clamp knob features a slip mechanism that prevents over tightening of the clamp.

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ACKNOWLEDGMENTS

TSgt Allen Jones would like to thank those who helped and provided advice during the evaluation of the IVAC MedSystem III and IVAC AC Power Adapter, Model 1555. He would especially like to thank:

LtCol Jacqueline Hale:	Flight Nurse/Program Manager
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Mr Douglas Townsend:	Electronics Engineer

TESTING AND EVALUATION OF THE IVAC MEDSYSEM III MULTI-CHANNEL INFUSION PUMP AND IVAC AC POWER ADAPTER, MODEL 1555

BACKGROUND

The IVAC Medical Systems, Inc. requested Aeromedical Research to evaluate and approve the IVAC MedSystem III and IVAC AC Power Adapter, Model 1555 for use on board USAF aeromedical evacuation aircraft and for use in the Department of Defense Deployable Medical Systems. Specific components of the IVAC MedSystem III evaluated included the IVAC MedSystem III, IVAC 28 series administration sets, and IVAC AC Power Adapter, Model 1555. All components of the IVAC MedSystem III were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the IVAC MedSystem III, IVAC 28 series administration sets, and IVAC AC Power Adapter, Model 1555.

DESCRIPTION

The EUT is a multichannel infusion pump which has three independent fluid delivery systems in the space of one. EUT provides an accurate delivery of a variety of fluids, and uses administration sets that provide free-flow protection. EUT displays infusion status for rate, volume remaining and volume infused. The rate range is from 0.1 - 999 milliliter per hour on each channel. Infusions can be programmed to deliver at a specified rate or over a specified period of time. Secondary mode allows fluids and medication to be delivered sequentially at two different rates. Configuration parameters allow the user to essentially have six available device types to achieve specific clinical applications: General Purpose, Neonatal, Controller Pressure, Operating Room, General Purpose II, Operating Room II. The different parameters include minimum rates, baseline and minimum volumes, baseline and maximum pressures, and air-in-line thresholds. The EUT operates on 115 VAC / 60 Hz, and an internal rechargeable battery pack (Figure 1). The EUT weighs approximately 5.1 lbs (2.32 kgs), and is 6 in. W. X 7.875 in. H. X 2.10 in. D. The EUT has an integral pole clamp that may be secured to a NATO litter handle (pole) or a C-9 litter stanchion. The clamp knob features a slip mechanism that prevents over-tightening of the clamp.

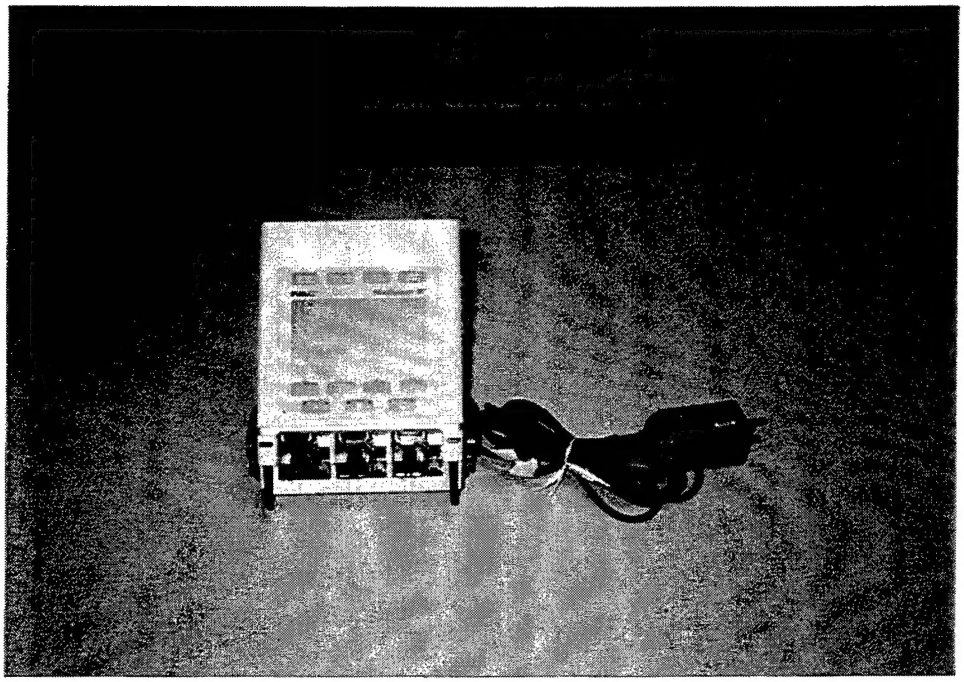


Figure 1. IVAC MedSystem III and IVAC AC Power Adapter, Model 1555.

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. NOTE: The EUT performance was evaluated only in the General Purpose mode of operation. Unless otherwise noted, all testing is conducted and monitored by Aeromedical Research personnel assigned to the Flight Stress Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/Humidity Environmental Conditions, encompassing:

a. Hot Operation

b. Cold Operation

c. Humidity Operation

d. Hot Temperature Storage

e. Cold Temperature Storage

5. Hypobaric Conditions

a. Cabin Pressure/Altitude

b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (2); AFI 41-201, Equipment Management in Hospitals (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).

d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was placed on a level surface at a 45 degree angle to simulate the angle of being clamped to a NATO litter, and operated from 115V AC power. An IVAC 28 series administration set was connected to an irrigation or intravenous (IV) solution bag and primed. The set was then loaded in the EUT in accordance with the operator's manual. The EUT was programmed for the following settings: channel A - 10 cc/hr, channel B - 100 cc/hr, and channel

C - 200 cc/hr. The tubing at the end of administration set was connected into 3-way stopcock. One end of the 3-way stopcock was connected to a Datrend Infutest Model 2000 Infusion Pump Analyzer using a 20 inch extension set, figure 2. The other port of the 3-way stopcock was used for priming/ flushing the IV pump analyzer. The IV pump analyzer was then programmed for the single-rate test for the rate accuracy evaluation.

In addition to the single-rate test, a volume accuracy evaluation was conducted. The tubing at the end of administration set was disconnected from the 3-way stopcock and placed in glass beakers. A calibrated A.N.D.™ HR-200 balance was used to weigh small volumes during the 10 ml evaluation.

Note: The Infutest 2000 can only be used with distilled water, therefore, sterile water was used to evaluate the rate and volume accuracy. In the altitude chamber and on the aircraft irrigation and a combination of IV fluids were used. The following solutions that were used were Sterile Water, Dextrose 5% in Water (D5W), Lactated Ringers (LR), 0.9% Saline, and Total Parenteral Nutrition (TPN).

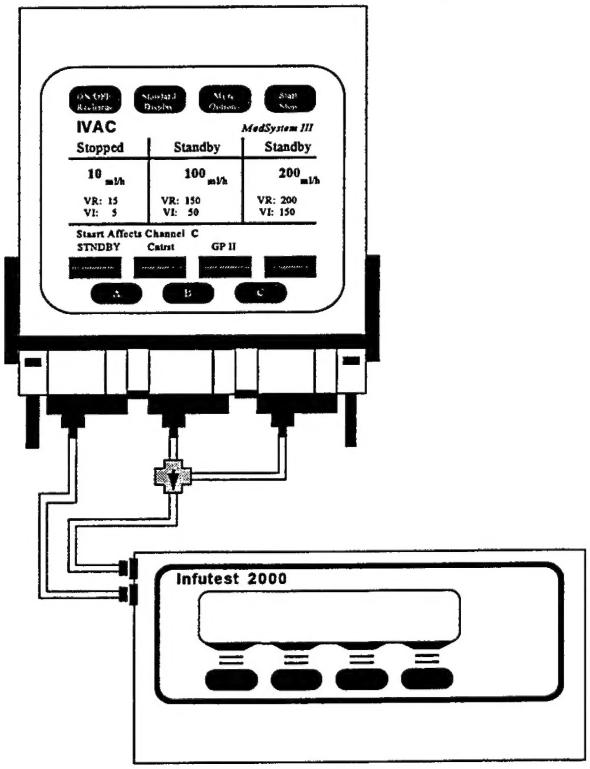


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions. The rate indicated in the single rate test was documented

during the rate accuracy evaluation while infusing the programmed settings of 10 cc/hr, 100 cc/hr, and 200 cc/hr. The tubing at the end of administration set was disconnected from the 3-way stopcock and placed in glass beakers. The EUT's infusion volume was collected in glass beakers, measured, and the infusion time was recorded. Small volumes were weighed on an A.N.D.™ HR-200 balance during the small volume, 10 ml, evaluation. The performance check was repeated three times to ensure the validity of test results. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison.

Battery Operation as outlined in IVAC Medical Systems Inc., Directions For Use (9) - The battery pack can be recharged from the external 115V AC / 60 Hz source in 16 hours. A full charge lasts a minimum of 6 hours.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments." (6) Testing was conducted using a calibrated Unholtz-Dickie Vibration System, controller model UD-VWIN and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT's components were mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft (Figure 3). They were subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

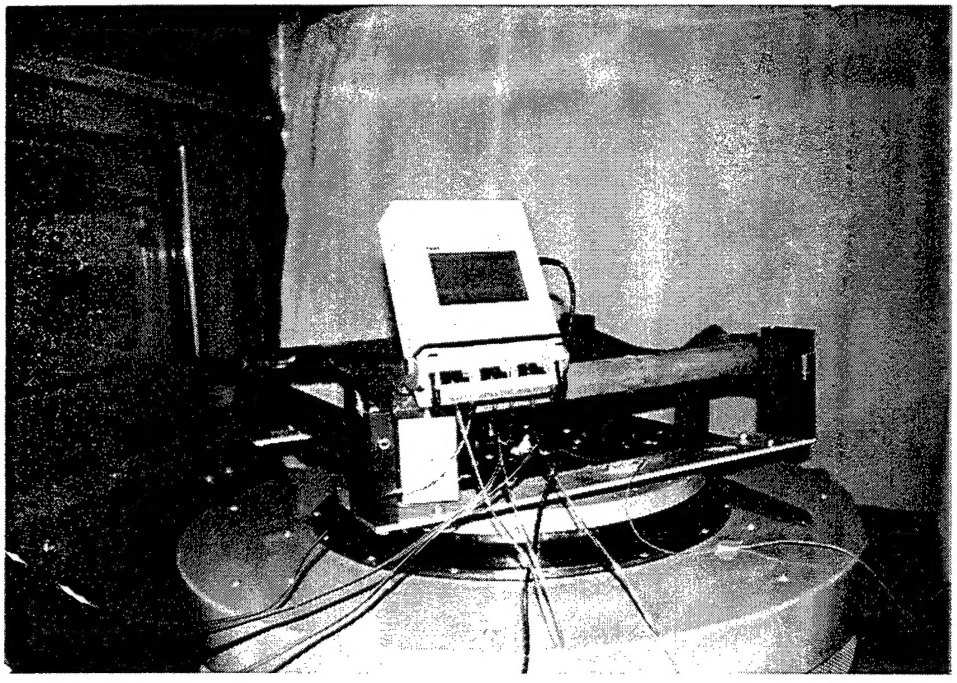
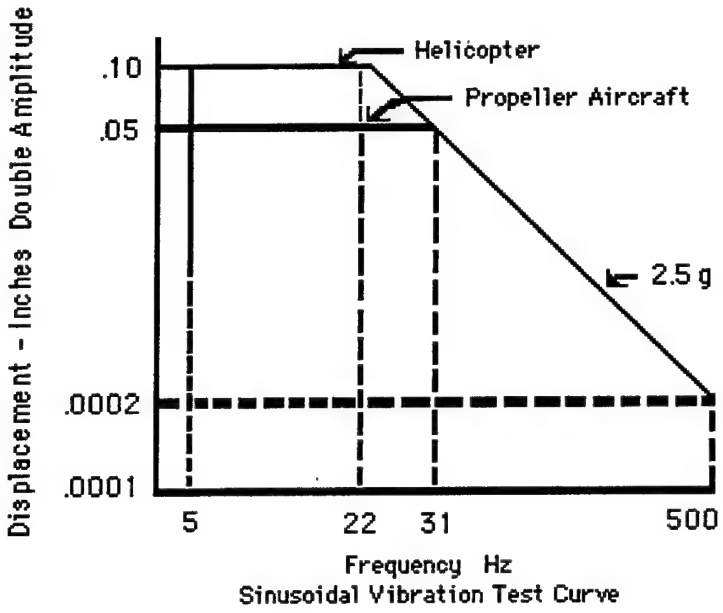


Figure 3. Vibration Table Mounting



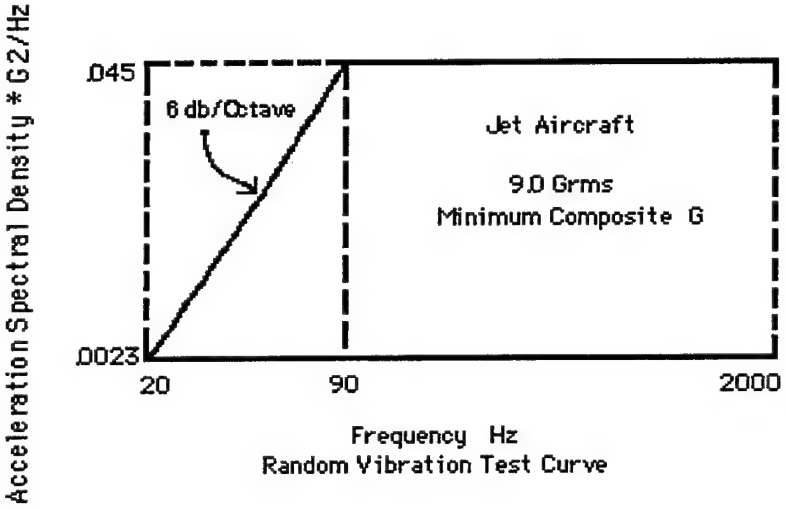


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions and potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). Electromagnetic compatibility testing was conducted at Southwest Research Institute in San Antonio, Texas except for the CS115 test. The EUT was operated and data collection was obtained by Aeromedical Research personnel. ASC/ENAI engineers at Wright-Patterson AFB conducted the CS115 test and evaluated all the electromagnetic compatibility data and determined the airworthiness of the EUT. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 1 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the device's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 120 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 200 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances." During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT operated in the maximum vacuum mode. For susceptibility testing, the EUT was operated again in the maximum vacuum mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC/60 Hz and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance"(6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in a calibrated Thermotron Industries, Model SM-32 Environmental Chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their

cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then, the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-9 aeromedical evacuation missions and a C-130 aeromedical readiness mission. On the C-9 the EUT was positioned and secured to a NATO litter handle (pole), and the console stanchion. On the C-130 the EUT was positioned and secured to a NATO litter handle (pole). Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification using intravenous (IV) fluids and total parenteral nutrition (TPN). Electrical safety test results showed all parameters to be within referenced guideline limits. Battery endurance met the manufacturer's specifications.

VIBRATION

In the X axis, the EUT operated within 10% of preset values and no alarm conditions occurred during operation. In the Y axis the EUT operated within 10% of preset values and an occlusion alarm condition occurred during operation. The channel was reset and no further alarm condition occurred. In the Z axis, the EUT operated within 5% of preset values and no alarm conditions occurred during operation. However, during operation in this axis the EUT slid periodically which required readjusting of the position and hand tightening of the pole clamp. These were not considered failures since these anomalies were transient in nature and could be corrected by a crewmember in flight.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from 115 VAC / 60 Hz & battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during all five phases of testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed to the manufacturer's specification using irrigation, intravenous (IV), and total parenteral nutrition (TPN) fluids.

2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-9 aeromedical evacuation mission, and a C-130 aeromedical readiness mission. The EUT did not slide while secured to the litter or on the litter stanchion. Excessive air-in-line occurred when the EUT was secured to the middle litter and the tubing was routed to the simulated patient on the bottom litter. This occurred due to negative pressure on the membrane in the tubing cassette. This anomaly did not occur when the EUT was at the same level as the simulated patient. Analysis of performance data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. Evaluation confirmed that the unit operated successfully during all phases of flight while secured at the same level as the patient.

SUMMARY

Aeromedical Research found the IVAC MedSystem III and IVAC AC Power Adapter, Model 1555 to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating in the General Purpose mode of operation on 115 VAC / 60 Hz or battery power with the recommendations listed below. Its operation was within expected parameters when subjected to vibration, electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression.

1. Position infusion pump at the same level as the patient or attach pump to the patient's litter.
2. Use on AC power when possible to conserve battery power

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

2. AFI 41-203, Electrical Shock Hazards

3. AFI 41-201, Equipment Management in Hospitals

4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. Emergency Care Research Institute (ECRI)

6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.

7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

8. MIL-STD-462 D, Measurement of EMI Characteristics.

9. IVAC Medical Systems, Inc., IVAC MedSystem III Directions For Use.

10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF THE IVAC MEDSYSTEM III AND MODEL 1555 AC POWER ADAPTER

SPECIFICATIONS

Dimensions:	Height: 7.875 inches (20.00 centimeters) Width: 6 inches (15.24 centimeters) Depth: 2.10 inches (5.33 centimeters)
Weight:	5.1 pounds (2.32 kilograms)
Case Material:	Impact resistant polycarbonate/ABS alloy
Air-In-Line:(Default)	500 µl except for Neonatal which is 50 µl
Occlusion Pressure:(Default)	15 psi except for controller pressure device which is 3 ft H_2O
System Accuracy:	±5%
Administration Sets:	IVAC MedSystem III 28 or 25 Series Sets
Operating Temperature:	50°-104° Fahrenheit (10°-40° Celsius)
Storage Temperature:	<95° Fahrenheit (<35° Celsius) for optimum battery life
Maximum Storage Temperature:	131° Fahrenheit (55° Celsius)
Rate Range:	0.1 - 999 milliliter per hour (each channel)
Volume Range:	0.1 - 9999 milliliter (each channel)
KVO Rate Range:	0.1 - 20 milliliter per hour

(Note: 4-20 ml/h KVO rate may be attained by using the field maintenance software)

AC Adapter:	Use only the IVAC AC Power Adapter, Model 1555
Power Consumption:	6 watts AC power
Batteries:	Main - Rechargeable NiCd Battery Pack Memory Back-up - Non-rechargeable Lithium
Battery Charge:	A fully charged battery has a minimum of 6 hours running time with all channels running at 125 milliliters per hour and backlighting usage of 2 minutes per hour. The main battery retains 80% of its capacity after 500 charging cycles, and retains 90% of its capacity after 3 months of continuous AC charging.
Fuses:	3 amp fast-blow internal
Ground Continuity:	Maximum 0.1 ohm
Leakage Current:	Maximum 100 microamps

Programmable Device Types (Configurations):

Default Parameter	**General Purpose**	**Neonatal**	**Controller Pressure**	**Operating Room**	**General Purpose II**	**Operating Room II**
Occlusion Detection Method	Baseline	Baseline	Absolute Threshold	Baseline	Baseline	Baseline
Occlusion Alarm Setting	Baseline +5 psi	Baseline +3 psi	Absolute 3 ft H_2O	Baseline +5 psi	Baseline +5 psi	Baseline +5 psi
Maximum Pressure	15 psi	15 psi	3 ft H_2O	15 psi	15 psi	15 psi
Air-In-Line Alarm Threshold	500 µl	50 µl	500 µl	500 µl	500 µl	500 µl
KVO Rate*	3 ml/h	1 ml/h	3 ml/h	3 ml/h	3 ml/h	3 ml/h
Rate Range	1-999 ml/h	0.1-99.9 ml/h	1-299 ml/h	1-999 ml/h	0.1-999 ml/h	0.1-999 ml/h
Maximum VR (Volume Range)	9999 ml	9999 ml	9999 ml	9999 ml	9999 ml	9999 ml
Pump Not In Use Advisory	Yes	Yes	Yes	No	Yes	No
ALL Setting for VR	N/A	N/A	N/A	Option	N/A	Option

**Channel will infuse at the KVO rate shown in the table or at the current infusion rate, whichever is lower.*